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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/416,267	10/12/1999	KUI SU	PF270P1	5938

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/10/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/416,267

Applicant(s)
Su et al.

Examiner
Premia Mertz

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 10, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-79 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Art Unit: 1646

DETAILED ACTION

1. Claims 1-24 have been canceled previously. Claims 25-79 are under consideration.
2. Receipt of applicant's arguments filed in Paper No. 19 (12/10/02) is acknowledged.
3. Applicant's arguments filed in Paper No. 19 (12/10/02), have been fully considered but were non-persuasive. The issues remaining are stated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 101

5. Claims 25-79 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 3-5 of the previous Office action (Paper No. 10, 9/7/00), pages 2-6 of the previous Office action (Paper No. 13, 5/8/01) and pages 2-8 of the previous Office action (Paper No. 18, 9/16/02).

Applicants argue that a rejection under 35 USC § 101 is proper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention. Furthermore, Applicants argue that they need only make one credible assertion of utility for the claimed invention to satisfy 35 USC § 101. However, contrary to Applicants arguments, simply asserting that the instant protein may stimulate cell proliferation and/or differentiation and may be used to treat, for example, restenosis and/or inflammation (page 3, lines 5-8) and that the polypeptides of the instant invention have further

Art Unit: 1646

related uses, for example, in the detection of neoplasia (page 37, lines 7-13) is insufficient, because Applicants have failed to demonstrate the effect of the claimed protein on cells. The instant situation is analogous to the "orphan receptors" situation (Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001, see Example 12). Applicants are reminded that an invention must be complete as filed. Applicants assert that the present case involves a polypeptide which has been described in the Graf et al and Oelgeschlager et al teachings (published in 2000, after the filing date of the instant invention) that the polypeptide of the instant invention shares 100% sequence identity with the human homologue of the *twisted gastrulation* protein from *Drosophila melanogaster*, that in the fruitfly this polypeptide is a secreted protein which functions by direct interaction with BMPs. However, based on the specification as filed, there is no disclosure of what the protein does or what it can do. There is no practical utility of the claimed protein in currently available form. Furthermore, no specific disease to be treated, has been enabled by Applicants, using the claimed protein and neither have Applicants demonstrated the clinical effects of potential agonists or antagonists of the protein. Therefore, the instant invention is not useful in currently available form because the instant compound has not been used clinically and the use of the instant protein cannot be foretold with certainty.

Applicants argue that the claimed polypeptide has⁵ been demonstrated to function similarly in fruit flies, amphibians and humans and have cited Ross et al (published in 2001) in this regard. However, contrary to Applicants arguments, even though applicants show (although not in the instant specification as filed) that the protein is conserved among species, Applicants have failed to show "in

Art Unit: 1646

the instant specification", the practical benefit of the protein of the instant invention as filed. The Examiner is not questioning the fact that the instant protein is a member of the family of proteins "which antagonize BMP signaling" but that the protein has a "specific function" in the application as filed. The Examiner's position is that this member of the protein family does not have a specific utility because the specific function of this particular protein has not been demonstrated in the instant application. The Examiner has presented a logical explanation that Applicants assertions are flawed. Applicants have failed to disclose what specifically the instant protein does. What is the physiological activity of the polypeptide of the instant invention?

The Brenner case has been cited previously for the position that a substantial, specific utility of the claimed protein is required. There is no specific condition disclosed for which the product can be used. This requirement is analogous to basic scientific characterization, however, in the instant case no substantial benefit for the polypeptide is currently disclosed, but an exploratory significance. In the absence of a knowledge of the biological significance of the polypeptide, there is no immediately obvious "patentable" use for it. Since the instant specification does not disclose a "real world" use for the claimed protein, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

Claims 25-79, also remain rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Claims 25-79 stand rejected under 35 U.S.C. § 112, first paragraph, because the instant specification does not teach how to use the invention for those reasons of record set forth at pages 3-5 of the previous Office action (Paper No. 10, 9/7/00),

Art Unit: 1646

pages 2-6 of the previous Office action (Paper No. 13, 5/8/01) and pages 2-8 of the previous Office action (Paper No. 18, 9/16/02).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

Art Unit: 1646

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
December 31, 2002